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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,776	08/23/2000	John Burczak	DEX-0079	2610

7590 06/18/2003

Jane Massey Licata  
Law Offices of Jane Massey Licata  
66 E Main Street  
Marlton, NJ 08053

EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/18/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/622,776

Applicant(s)  
Burczak et al

Examiner  
Unger

Art Unit  
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 16, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11, 12, and 16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 12, and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2003 (Paper No. 16) has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action

*New Grounds of Objection*

3. Claims 16, 11-12 are objected to because the preamble of claim 16 recites a method of monitoring progression of ovarian or testicular cancer in a patient, but the body of the claim is drawn to measuring biological samples obtained from a patient at selected times. It appears that the limitations of the claims are not drawn to a patient who has ovarian or testicular cancer, but rather only to "a patient". The objection can be obviated by amending section (a) of claim 16 to recite, for example, "measuring.....from said patient at selected times".

*Claim Rejections - 35 USC § 103*

4. Claims 16, 11, 12 are rejected under 35 USC 103, essentially for the reasons previously set forth in Paper No. 6, Section 8, pages 11-14 drawn to the rejection of claims 13-15, which were canceled in Paper No. 8. The claims are rejected as being unpatentable over Yamashita et al (Clin. Chim. Acta).

The claims are drawn to a method of monitoring progression of ovarian or testicular cancer comprising measuring PLA2 levels in biological samples wherein an increase in the measured levels of PLA2 in the patient over time is indicative of

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progressive ovarian or testicular cancer, a decrease in the measured levels of PLA2 in the patient over time is indicative of remission or response to therapy of the ovarian or testicular cancer and no change in the measured levels of PLA2 in the patient is indicative of stabilization of the ovarian or testicular cancer, wherein the biological samples are serum, wherein the measuring is by ELISA.

Yamashita et al teach that serum samples of patients, with lung cancer, breast cancer, esophageal cancer, gastric cancer, colorectal cancer, liver cancer, bile duct cancer, pancreatic cancer were tested for overexpression of PLA2. Instances of overexpression of PLA2 compared to normal control in serum were found in every single one of the eight cancer types tested (See Figure 1, p. 94). Examiner takes note that the art recognizes that all of the cancer types tested are known to be either carcinomas or include a subset of carcinomas within the genus. Yamashita et al further teach a method of monitoring response to therapy in patients with cancers in liver, esophagus, colon, pancreas and stomach by ELISA assay of PLA2 expression in serum two weeks after resection and wherein it was found that all in nine patients tested, that is in each of the cancer types tested, there was a reduction in PLA2 levels in the serum (see Figure 3, page 96 and page 97). Yamashita further teach the relationship between serum PLA2 levels and tumor progression and teach specifically that breast cancer patients with T2-T4 or Stage II-IV cancers have significantly higher levels of PLA2 in comparison with T1 or stage I cancers of the same type and that breast cancer patients with lymph node involvement (metastasis) or distant metastasis had significantly higher serum PLA2 than those that did not (see pages 95 and 96 and Figure 3). Yamashita et al teach as set forth but do not

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teach a method of monitoring progression of ovarian or testicular cancer, remission, response to therapy of ovarian cancers or testicular cancer.

It would have been *prima facie* obvious to one of ordinary skill in the art, and one would have been motivated, at the time the invention was made to modify the assay of Yamashita et al to monitor the progression of ovarian or testicular cancer (both of which cancer types include carcinomas) in a patient because Yamashita et al specifically teach that a wide variety of cancer types, all of which include carcinomas, demonstrate elevation of PLA2 in serum compared to normal control and it would be expected that at least a subset of ovarian and testicular cancers, carcinomas, would also present with elevation of PLA2 in serum compared to normal control. One would have a reasonable expectation of success in monitoring the progression of a subset of ovarian and testicular cancers, carcinomas, because just as every single one of the cancer types tested by Yamashita et al, presented with elevated serum PLA2, every single one of the cancer types tested showed a reduction in those levels after treatment. Thus it would be expected that the same effect would be seen in a subset of ovarian and testicular cancer types, carcinomas. Further, since remission is by definition a reduction of cancer load and the therapy here is resection which is reduction of tumor load, it would have been obvious to, and one would have been motivated to and would have expected to successfully monitor for remission with the modified method of Yamashita. Finally, it would have been *prima facie* obvious and one of ordinary skill in the art would have been motivated to modify the assay of Yamashita to monitor progression of ovarian and testicular cancer because it is clear that the active cancer is responsible for the

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overexpression of the PLA2 and since recurrence is a form of progression, it would have been expected that recurrence would present with increased expression of PLA2 in serum and it would be obvious and one would be motivated to and expect to successfully monitor progression by the modified method of Yamashita by assaying for the return of elevated levels of PLA2. Given the above, one would have a reasonable expectation of success in monitoring progression in at least a subset of testicular and ovarian cancers.

5. All other objections and rejections recited in Paper No. 3 are withdrawn.
6. No claims allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

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Susan Ungar  
Primary Patent Examiner  
June 17, 2003

A handwritten signature in black ink, appearing to read "Susan Ungar", written over the printed name and date.